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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Civil Action No. 10-6108 (ES)(CLW)

(Filed Electronically)

**JAZZ'S MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION TO CONSOLIDATE ACTIONS**

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Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") submits this memorandum of law in support of its motion pursuant to Fed. R. Civ. P. 42(a) and Local Civ. R. 42.1 to consolidate Civil Action Nos. 10-6108 and 12-6761 pending before this Court. In support of its Motion, Jazz also submits the accompanying Declaration of Gabriel P. Brier.

I. INTRODUCTION

The two actions that Jazz seeks to consolidate share common issues of law and fact. Both are patent infringement cases arising under the Hatch-Waxman Act. Both cases allege infringement of patents in the same patent families with the same inventors. Both cases relate to the same defendant and the same accused product.

The similarity and overlap of issues make these cases suitable for consolidation. The documents requested and already produced in the earlier-filed action will be nearly identical to those produced in the later-filed action. Witness testimony at deposition and trial (e.g., inventor and expert testimony) will invariably be the same. The infringement and validity arguments in both cases are essentially equivalent and will involve consideration of the same accused product, prosecution histories, prior art, and expert testimony. Consolidation will promote judicial economy by avoiding duplicative litigation over patents in the same family and eliminating the risk of divergent rulings. Consolidation will not prejudice Roxane because, to the extent that a minimal amount of discovery is necessary in the later-filed action, that discovery can be accomplished relatively quickly. [REDACTED]

[REDACTED]

[REDACTED] Accordingly, as discussed further below, the balance of the relevant factors in this case all favor consolidating the actions.

II. BACKGROUND

Jazz markets the drug product XYREM[®] for the FDA-approved indications of treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. XYREM[®] is an oral solution containing 500 mg/mL of the active pharmaceutical ingredient sodium oxybate, which is also known as sodium gamma-hydroxybutyrate or “GHB.” Defendant Roxane Laboratories, Inc. (“Roxane”) has filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to market a generic version of XYREM[®]. As part of its ANDA, Roxane provided certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that Jazz’s patents listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (“the Orange Book”), with respect to XYREM[®] are invalid, unenforceable, and/or not infringed by Roxane’s ANDA product (“Roxane’s Paragraph IV Certifications”). Based on Roxane’s Paragraph IV Certifications, Jazz brought four lawsuits against Roxane for infringement of Jazz’s Orange-Book-listed patents, plus one additional patent.¹

The patents-in-suit include those from Jazz’s ’431 patent family.² The inventors are the same for all of the patents in the ’431 patent family. The ’889, ’219, and ’506 patents currently in suit—and the ’650 patent that Jazz seeks to consolidate—all issued from divisional or continuation patent applications filed in a chain that claim priority back to the ’431 patent. In

¹ The four actions are *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(CLW), *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 11-660 (ES)(CLW), *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 11-2523 (ES)(CLW), and *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 12-6761 (ES)(CLW). This Court previously Ordered consolidation of Civil Action Nos. 11-660 and 11-2523 with Civil Action No. 10-6108. D.I. 27; D.I. 49.

² The ’431 patent family refers to U.S. Patent Nos. 6,472,431 (“the ’431 patent”), 6,780,889 (“the ’889 patent”), 7,262,219 (“the ’219 patent”), 7,851,506 (“the ’506 patent”), and 8,263,650 (“the ’650 patent”).

other words, all of the patents in the '431 patent family ultimately claim priority to the same application. This means that the patents share the same specification or written description of what has been invented. Thus, the claims of the '431 patent family all derive from the same common set of facts.

Here, Jazz seeks consolidation of its lawsuit alleging infringement of the '650 patent—the most recently issued patent in the '431 patent family—with its earlier-filed lawsuits based upon the other patents in the '431 patent family. The claims of the '650 patent are directed towards pharmaceutical compositions containing sodium oxybate at certain concentrations and pH, and that are chemically stable, resistant to microbial growth, and free of preservatives. (Ex. A, at col. 70 lns. 28-67.)³ The '650 patent also contains claims to methods of using the claimed pharmaceutical compositions to treat cataplexy or daytime sleepiness. (*Id.*) The claims of the other patents in the '431 patent family concern substantially similar subject matter:

- the '431 patent claims are directed towards methods of making pharmaceutical compositions containing sodium oxybate having certain concentrations and pH that are chemically stable, resistant to microbial growth, and free of preservatives (Ex. B, at col. 70, lns. 5-28);
- the '889 and '219 patent claims are directed towards pharmaceutical compositions containing sodium oxybate having certain concentrations and pH, and that are chemically stable, resistant to microbial growth, and free of preservatives (Ex. C, at col. 64, lns. 30-36; Ex. D, at col. 76, ln. 54 to col. 78, ln. 3);
- the '506 patent claims are directed towards methods of using pharmaceutical compositions containing sodium oxybate having a certain concentration to treat various conditions, including cataplexy (Ex. E, at col. 72, lns. 19-37).⁴

Fact discovery has closed in the earlier-filed action, Civil Action 10-6108. This Court issued its *Markman* Opinion and Order in that action on September 14, 2012. Expert discovery has been stayed pending resolution of Jazz's motion to consolidate and a co-pending request by

³ "Ex. __" refers to exhibits to the accompanying Declaration of Gabriel P. Brier.

⁴ On December 4, 2012, a sixth patent is scheduled to issue in the '431 patent family, U.S. Patent No. 8,324,275 ("the '275 patent"). (Ex. F.) The '275 patent is addressed further below.

Roxane for leave to amend its invalidity and noninfringement contentions. This Court has yet to set a date for the final pretrial conference or trial.

Jazz filed its Complaint in the later-filed action, Civil Action No. 12-6761, on October 26, 2012. Roxane filed its Answer and Counterclaims on November 9, 2012. Jazz filed its Reply to Roxane's Counterclaims on November 16, 2012.

III. ARGUMENT

A. Legal Standard

"Pursuant to Fed. R. Civ. P. 42(a), a court may consolidate actions before it if said actions 'involve a common question of law or fact.'" *Thomas v. Gerber Prods. Co.*, No. 12-835, 2012 WL 1606627, at *2 (D.N.J. May 8, 2012) (quoting Fed. R. Civ. P. 42(a)); *see also*, *Surgical Ctr. of North Brunswick v. Aetna Health, Inc.*, No. 12-3678, 2012 WL 4120777, at *1 (D.N.J. Sept. 19, 2012). Courts consolidate cases to "streamline and economize pretrial proceedings so as to avoid duplication of effort, and to prevent conflicting outcomes in cases involving similar legal and factual issues.'" *Gerber Prods.*, 2012 WL 1606627, at *2 (quoting *In re TMI Litig.*, 193 F.3d 613, 724 (3d Cir. 1999)). More specifically, when deciding whether or not to consolidate the cases, "the court must balance the risk of prejudice and possible confusion against the risk of inconsistent adjudications of common factual and legal issues, the burden on the parties and witnesses, the length of time required to conclude multiple lawsuits as against a single one, and the relative expense to all concerned" *Surgical Ctr. of North Brunswick*, 2012 WL 412077, at *1 (quoting *A.F.I.K. Holding SPRL v. Fass*, 216 F.R.D. 567, 570 (D.N.J. 2003)). When actions involve the same parties and allege the same claims, they raise "substantially identical issues that should be litigated together to best ensure judicial economy." *See Gerber Prods.*, 2012 WL 1606627, at *2 (holding that consolidation of cases is proper where

all actions were brought by the same party, involve the same claims, and are directed at the same product); *see also Surgical Ctr. of North Brunswick*, 2012 WL 412077, at *1 (same).

B. This Court Should Exercise Its Discretion to Order Consolidation In the Interests of Judicial Economy and Because No Factors Weigh Against Consolidation

1. Consolidation Is Appropriate When Two Patent Infringement Actions Concern Substantially Similar Claims and Defenses

Where there is a common question of law or fact, “the decision to consolidate rests in the sound discretion of the district court.” *CIMA Labs, Inc. v. Actavis Group HF*, No. 06-1970, 2007 WL 1672229, at *6 (D.N.J. June 7, 2007) (citation omitted); *see also Medpointe Healthcare, Inc. v. Hi-Tech Pharmacal Co., Inc.*, No. 03-5550, 2007 WL 188285, at *4 (D.N.J. Jan. 22, 2007) (consolidating cases for discovery and liability after balancing the savings of time and effort gained from consolidating against the inconvenience, delay or expense that might result from simultaneous disposition of separate actions). With respect to common issues regarding infringement, the same questions concerning whether Roxane’s ANDA product meets the limitations of the ’431, ’889, ’219, and ’506 patents also apply to the ’650 patent. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Further, resolving Roxane’s allegations regarding the alleged invalidity of the claims of the ’431 patent family will involve the same evidence as Roxane’s allegations concerning the ’650 patent. Indeed, six of the nine references cited in Roxane’s notice letter of its Paragraph IV Certification concerning the alleged invalidity of the ’650 patent have already been cited by Roxane in its invalidity contentions in the earlier-filed case. The other three references raise no

new issues that were not already in dispute.⁵ Thus, there can be no dispute that common questions of law and fact exist in these two actions. Accordingly, consolidation is favored here, where both actions involve consideration of the same accused product, prosecution history, prior art, and expert testimony. *See Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 06-514, 2007 WL 2892707, at *4 (D. Del. 2007) (granting consolidation motion when patents in two actions were related to the same technology and shared many similar claims, and the same product was accused of infringement in both actions).

Considering the significant overlap of the infringement and invalidity issues in these two actions, there is great potential for judicial *inefficiency* if consolidation is denied. Absent consolidation, there would be separate, duplicative rounds of expert reports, expert discovery, pretrial orders, and trial on the issues. At each of these stages, the parties' and the Court's resources would be wasted by reengaging issues that should have been addressed together. Further, the parties' experts, the inventors of the patents-in-suit (who no longer work for Jazz), and other third parties would incur the extra time and expense of attending two trials, rather than one. Such duplication of efforts by the parties and the Court is not warranted when the option to consolidate exists. *See Internet Law Library, Inc. v. Southridge Capital Management, LLC*, 208 F.R.D. 59, 61 (S.D.N.Y. 2002) (consolidation prevents the inefficiency caused by duplicative pretrial proceedings and multiple trials). Given the extensive overlap of issues in these actions, consolidation should be granted in the interests of judicial economy.

⁵ Roxane may argue that its allegation of inequitable conduct concerning the '650 patent raises new issues not at issue in the earlier filed action. But that allegation concerns a reference already at-issue in the earlier action. If that reference is not found but-for material to patentability, i.e., invalidating, then there can be no finding of inequitable conduct. *See Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1291-1292 (Fed. Cir. 2011). Thus, if the reference is not invalidating in the earlier action, then Roxane will be hard-pressed to argue that it forms the basis of an inequitable conduct finding in the later-filed action.

2. Balancing of the Remaining Factors Supports Consolidation

A balancing of interests to determine whether to consolidate includes considering “the risk of prejudice and possible confusion” against the risk of inconsistent adjudications of common factual and legal issues, and the certainty of additional burden and expense of multiple lawsuits. *A.F.I.K. Holding SPRL*, 216 F.R.D. at 570. Here, consolidation will not result in undue delay, as fact discovery already completed in the earlier-filed action will be pertinent to the later-filed action concerning the ’650 patent. Completion of contentions concerning the ’650 patent under the Local Patent Rules will take approximately two months. *See* L. Pat. R. 3.6. Limited additional discovery concerning the ’650 patent could be completed in another month or two. Further, given their similarity to the other claim terms in the ’431 patent family, there do not appear to be any claim terms in the ’650 patent that would require construction.⁶ Thus, there is minimal potential for delay if these actions are consolidated.

As Roxane has already acknowledged, the earlier-filed action will not be ready for trial when the existing 30-month statutory stay of FDA approval expires in April 2013. (Ex. G, Oct. 2, 2012 Status Conf. Tr. at 5:2-3.) [REDACTED]

[REDACTED] Last, but not least, there has been no expert discovery in the earlier action. There can be no prejudice to Roxane when the original action will not be trial-ready anytime soon [REDACTED].

Moreover, the fact that the new case and the existing case are at different stages of proceedings is not dispositive. *See Smithkline Beecham Corporation v. Geneva Pharma.*, No. 99-2926, 2001 WL 1249694, at *5 (E.D. Pa. Sept. 26, 2001) (granting motion to consolidate

⁶ Even if a few terms did require construction, expedited *Markman* proceedings could be completed in a relatively short period of time given that the scope of any remaining claim dispute would have to be limited. .

despite different stages of cases). Nor will adding the '650 patent lead to any possibility of confusion because this is a bench trial and the issues substantially overlap. Accordingly, neither risk of prejudice to Roxane nor any possibility of confusion weigh against granting consolidation of these actions.

C. The Soon-To-Be-Filed Action Concerning the '275 Patent Should Be Consolidated For the Same Reasons as the '650 Patent Action

Jazz's '275 patent is scheduled to issue on December 4, 2012. (Ex. F.) The application that became the '275 patent was filed on April 13, 2012 on an expedited basis and is a continuation in the chain of the '431 patent family. The '275 patent claims methods of treating cataplexy or daytime sleepiness in patients with narcolepsy by administering doses diluted from a 500 mg/mL concentrated solution of sodium oxybate. (Ex. H.) The claims of the '275 patent are substantially similar to the claims of the '506 patent already-in-suit relating to the treatment of narcolepsy patients with sodium oxybate solutions. (*See* Ex. E at col. 72:19-37.) Thus, issues of law and fact concerning the infringement and validity of the newly issued '275 patent are common to, and will be duplicative of, the issues already pending in the current action.

Jazz plans to list the '275 patent in the Orange Book and sue Roxane for infringement of the '275 patent immediately following its issuance. As the Court may recall, Roxane has acknowledged that it is tracking Jazz's pending patent applications and Roxane has been aware that the '275 patent will issue soon. Roxane, however, has indicated that it will not agree to consolidation of the '275 patent action with the current case.

Adding the '275 patent on the same grounds as the '650 patent will not cause undue delay. The final brief on this motion to consolidate is currently due on December 21, 2012. Assuming Jazz sues on the '275 patent promptly after it is issued, Roxane's Answer would likely be due before the Court has had much time to rule on Jazz's motion to consolidate the '650

patent action. Therefore, the procedural posture of the actions concerning the '650 patent and the '275 patent will likely be the same when this Court renders its decision on the present motion for consolidation. Certainly contentions and discovery concerning the '275 patent would be able to proceed concurrently with those concerning the '650 patent.⁷ Under these circumstances, if consolidation is granted with respect to the '650 patent action, then there will be no further delay in the proceedings by consolidating the '275 patent action. Accordingly, rather than conducting the two litigations in parallel, the action concerning the '275 patent should be consolidated with the actions concerning the '650 patent and the '431 patent family for the reasons discussed above. Therefore, Jazz respectfully requests that the Court's decision with respect to consolidation of the '650 patent action also apply to Jazz's '275 patent action.

IV. CONCLUSION

For the foregoing reasons, Jazz respectfully requests that this Court grant Jazz's motion to consolidate Civil Action Nos. 10-6108 and 12-6761, and further that the Court consolidate these actions with the action relating to Jazz's '275 patent.

⁷ Roxane should not be heard to complain that it would not have enough time to prepare contentions concerning the '275 patent. First, the issues involving the new patent overlap with issues that have been in the case from the beginning. Second, Roxane has been aware that the '275 patent was likely to issue soon for months, as it indicated at the status conference.

Respectfully submitted,

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